APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,202	12/27/2001	John M. Flack	MTS 0102 PUS	2844

22045	7590	09/12/2006

BROOKS KUSHMAN P.C.
1000 TOWN CENTER
TWENTY-SECOND FLOOR
SOUTHFIELD, MI 48075

EXAMINER
RINES, ROBERT D

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	**Applicant(s)**
Office Action Summary	10/036,202	FLACK ET AL.
	Examiner	**Art Unit**	
	Robert D. Rines	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1]   This communication is in response to the amendment filed 13 June 2006. Claims 1-19 are

pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[2]   Claims 1-19 are rejected under 35 U.S.C. 103(a) as being obvious in view of Pestotnik et

al. (United States Patent Application Publication #2004/0260666).

[A]   As per claim 1, Pestotnik et al. teaches a patient healthcare management system having a

capability to evaluate patient kidney function (Pestotnik et al.; Abstract, paragraphs [0024]

[0085]), the system configured to: receive input defining a patient's medical record including the

patient's demographic information, medical condition and diagnosis (Pestotnik et al.; paragraphs

[0010] [0024] [0083] [0085]); output at least one medical treatment recommendation wherein the

recommendation is based on the patient's medical record (Pestotnik et al.; Abstract and

paragraphs [0084] [0085] [0131]) and calculate and output at least one treatment goal for the

patient (Pestotnik et al.; paragraphs [0094] [0150] [0151]).

[i]   Pestotnik et al., teaches a system and method that gathers patient data, provides expert

system evaluation of patient data for the purpose of generating decision-supported patient data to

a physician. As taught by Pestotnik, deliverables to the physician include potential causes of the

patient's medical condition, mitigating factors based on one of more of the causes for the medical

condition, and providing the physician with at least one medical care recommendation (Pestotnik

et al.; paragraph [0028]). Among the exemplary patient input data taught by Pestotnik et al. are

the patient's medical history, family history, genetic susceptibilities, heart rate, blood pressure,

blood sugar level, and the like (Pestotnik et al.; paragraphs [0094] [0131] [0083]). Pestotnik

further teaches identifying whether the existing medical care is successful in treating the medical

condition based on current success of the regime (Pestotnik et al.; paragraph [0151]) and

providing warnings and alerts related to newly acquired or updated patient data (Pestotnik et al.;

paragraph [0098]), such as an undesirable change in blood pressure or blood sugar levels

(Pestotnik et al.; paragraph [0094]). Lastly, Pestotnik et al., teaches a system and method

intended to provide expert guidance to physician's regarding the diagnosis and treatment of renal

diseases (Pestotnik et al.; paragraph [0086]). Although Pestotnik et al., does not specifically

teach analysis of patient medical data to determine an estimated glomerular filtration rate, the

examiner interprets the above noted teachings of Pestotnik et al., to be inclusive of analysis of

kidney function and/or an associated filtration rate, in cases in which the Pestotnik method and

system are applied to the diagnosis and treatment Renal diseases and disorders.

[ii]   It would have been obvious to one of ordinary skill in the art at the time the invention

was made to have applied a system and method, with the above noted features and attributes of

Pestotnik et al., to assessing kidney function and associated medical parameters, e.g., filtration

rate, when motivated to diagnose and treat Renal diseases (Pestotnik et al.; paragraph [0085]).

[B]   As per claim 2, Pestotnik et al. teaches a system wherein the at least one treatment goal

for the patient comprises at least one of: a goal blood pressure, a goal lipid level, a goal

cholesterol level and a goal hemoglobin A1C level (Pestotnik et al.; paragraphs [0094] [0127]).

[C]   As per claim 3, Pestotnik et al. teaches a system additionally configured to receive input

specifying a treatment for the patient (Pestotnik et al.; Abstract and paragraph [0067] [0076])

[D]   As per claim 4, Pestotnik et al. teaches a system additionally configured to output an

indication as to whether, based on the patient's medical record, the at least one medical treatment

goal has been met (Pestotnik et al.; paragraphs [0094] [0151]).

[E]   As per claim 5, Pestotnik et al. teaches a system wherein a plurality of clinical treatment

algorithms are applied to the patient's medical record to generate the at least one treatment

recommendation and the at least one patient treatment goal (Pestotnik et al.; paragraphs [0084]

[0094] [0138] [0150] [0151]).

[F]   As per claim 6, Pestotnik et al. teaches a system additionally configured to: receive input

specifying a patient's current medication(s); receive input specifying a new prescription for the

patient (Pestotnik et al.; paragraph [0153]); and generate an alert if the prescribed medication

may antagonize a medication the patient is currently taking (Pestotnik et al.; paragraphs [0077]

[0154]).

[G]   As per claim 7, Pestotnik et al. teaches a system further configured to: receive input

defining a plurality of patient medical records comprising patient demographic information,

medical condition, diagnosis and treatment (Pestotnik et al.; paragraphs [0010] [0024] [0083]

[0085] [0116]); receive input defining at least one medical record parameter to extract from the

plurality of medical records (Pestotnik et al.; paragraph [0112]); and automatically generate a

report containing an aggregate of the at least one medical record parameter extracted from the

plurality of medical records (Pestotnik et al.; paragraphs [0026] [0094]).

[H]   As per claim 8, Pestotnik et al. teaches a system further configured to receive input

defining a subset of the plurality of patient medical records from which to extract the at least one

medical record parameter (Pestotnik et al.; paragraphs [0112] [0153]).

[I]   As per claim 9, Pestotnik et al. teaches a system additionally configured to receive input,

for each patient encounter with his or her healthcare provider (Pestotnik et al.; paragraphs [0127]

[0145]) defining the patient encounter wherein each defined patient encounter is appended to the

patient's medical record (Pestotnik et al.; paragraphs [0127] [0128]).

[i]   Regarding claims 2-9, the obviousness and motivation as discussed with regard to claim 1

above are applicable to claims 2-9 and are herein incorporated by reference.

[J]   Claims 10-18 differ from system claims 1-9 in that claims 10-18 are directed to a method.

As per this element, Pestotnik et al. teaches both a method and a system (Pestotnik et al.;

paragraphs [0012]-[0118] and [0027]).

[i]   The remainders of claims 10-18 repeat the same limitations of system claims 1-9, and are

therefore rejected for the same reasons given for those claims.

[K]   As per claim 19, Pestotnik et al. teaches a computer-based system for interactively

managing patient healthcare and evaluating patient kidney function, the system comprising: a

means for defining a patient's medical record (Pestotnik et al.; paragraphs [0010] [0024] [0083]

[0085]); a means for establishing the patient's estimated glomerular filtration rate based on the

patient's medical record (Pestotnik et al.; paragraphs [0084] [0085] [0094] [0137] *see analysis

claim 1); a means for generating at least one patient treatment recommendation based on the

patient's medical record and estimated glomerular filtration rate (Pestotnik et al.; Abstract and

paragraphs [0084] [0085] [0131] *see analysis claim 1); and a means for calculating at least one

treatment goal for the patient (Pestotnik et al.; paragraphs [0094] [0150] [0151]).

Regarding claim 19, the obviousness and motivation to combine as discussed with regard to

claim 1 above are applicable to claim 19 and are herein incorporated by reference.

Response to Remarks

Applicant's Remarks filed 13 June 2006 have been fully considered but they are not persuasive.

The arguments will be addressed below in the order in which they appear in the response filed 13

June 2006.

Applicant remarks:

Examiner first admits that Pestotnik "does not specifically teach analysis of patient medical data

to determine as estimated glomerular filtration rate..." (Office Action, pg. 4). Examiner then

"interprets" Pestotnik "to be inclusive of analysis of kidney function and/or an associated

filtration rate." Examiner's mere interpretation of a reference does not make clear that the

missing descriptive matter is necessarily present.

In response, the test for obviousness is not whether the features of the claimed invention must be

expressly suggested in any one or all of the references. Rather, the test is what the teachings of

the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981).

As cited in the Office Action mailed 9 March 2006 (incorporated by reference herein), Pestotnik

et al. disclose an expert system that allows for an evaluation of a patient over an extended period

of time without the need to re-input patient data each time a clinician examines same patient (i.e,

a medical records system). Pestotnik et al. further disclose that the Pestotnik invention gathers

patient data and evaluates the patient data to identify known or unknown medical conditions and

provide decision-supported data to a physician including guidance as to the potential medical

conditions of the patient and to aid the clinician in making informed decisions related to patient

medical care (Pestotnik et al.; paragraphs [0011] [0017] [0018]). Among the outputs of the

Pestotnik system are at least one medical diagnosis and at least one medical care

recommendation that are based upon a large expert knowledge base (Pestotnik et al.; paragraph

[0022]). Pestotnik et al. further disclose that the expert knowledge base is constructed from

information and data from experts within the relevant fields of medicine including Renal

diseases (Pestotnik et al.; paragraph [0085]). Using the expert system, the Pestotnik invention

generates solutions to known and unknown conditions of the patient (Pestotnik et al.; paragraph

[0090]). Lastly, when a therapeutic regimen is suggested, the Pestotnik system outputs pertinents

patient data including drug name and type, dose, route, interval and duration of therapy, and

demographics specific to the patient (Pestotnik et al.; paragraph [0094]).

Pestotnik's emphasis on determination of drug name and type, dose, and particularly route,

indicate to the Examiner that Pestotnik functionally enables predictive outputs indicative of a

patient's clearance rate of the proposed treatment/compound (e.g., as numerous compounds and

types of drugs are cleared or filtered from the individual's system by the kidneys). Further,

Pestotnik's identification of the system's applicability to renal diseases as a result of the expert

knowledge base including information and data derived from experts in renal diseases, indicates

to the Examiner that expert derived information would include particulars associated with renal

dysfunction including compromised filtration.

Applicant further remarks:

Applicant's "gui 234.....extracts information 236" and estimates the patient's glomerular filtration

rate using Equations 1 and 2, (pg. 22, lines 9-24), thus deriving additional information from the

"patient information 236".

In response, while Applicant points to specific equations employed by the Applicant to derive an

estimated glomerular filtration rate from input information limited to the patient's demographic

information, medical condition, and diagnosis (Applicant's Claim 1), Examiner respectfully

submits that the cited equations are not part of the invention as claimed in the present

application. Given that Pestotnik et al. applies to diagnoses of renal diseases and clearance rates of compounds (as noted above), and Pestotnik also references patient demographic information, medical conditions, and diagnoses, and further Pestotnik's describes numerous software modules that likely utilize equations in determining output information/recommendations to the physician, Examiner concludes that similar calculations and made possible by the Pestotnik system. However, Examiner points out that Applicant's specifically designated equations (Applicant's Specification) are absent in the teachings of Pestotnik.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RDR

9/5/06.